EXHIBIT 4

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (JLH)
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	

EXHIBIT 4

SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S DISPUTED FACTS FOR AFFIRMATIVE CASE

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In accordance with Local Rule 16.3(c) of the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, Sarepta Therapeutics, Inc. ("Sarepta") and the University of Western Australia ("UWA") (collectively, "Counter-Plaintiffs") provide a statement of the facts which Counter-Plaintiffs contend remain to be litigated.

By setting forth specific information herein, Counter-Plaintiffs do not intend to waive their right to prove information not specifically set forth herein. This statement is not intended to be exhaustive and, in addition to what is set out herein, Counter-Plaintiffs may prove any matters identified in their pleadings and discovery taken in this action to date.

The following statement is based on the parties' pleadings, documentary and testimony evidence, expert reports, and on Counter-Plaintiffs' current understanding of Nippon Shinyaku Co., Ltd.'s ("NS Japan") and NS Pharma, Inc.'s ("NS Pharma") (collectively, "Counter-Defendants") claims and/or defenses. Counter-Plaintiffs reserve the right to revise, amend, supplement, or modify the following statement based on any pretrial rulings by the Court and/or to address any additional issues, arguments raised by Counter-Defendants, evidence, or other developments in the case, including edits to the draft pretrial order, any meet and confers or other negotiations between the parties, pending motions, and similar developments. To the extent that Counter-Plaintiffs' Statement of Issues of Law to be Litigated set forth in Exhibit 6 contains issues of fact, those issues are incorporated herein by reference. Should the Court determine that any issue identified below is more appropriately considered an issue of law, Counter-Plaintiffs incorporate such issue by reference in Exhibit 6.

I. INFRINGEMENT OF THE WILTON PATENTS[1]

A. U.S. Patent No. 9,994,851

1. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Viltepso® (viltolarsen) literally meets each and every limitation of claim 1 and 2 of U.S. Patent No. 9,994,851 ("the '851 Patent").

2. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants directly infringe claims 1 and 2 of the '851 Patent by importing, offering to sell, and/or selling Viltepso® (viltolarsen) in the United States.

3. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants induce infringement of claims 1 and 2 of the '851 Patent, including:

- Whether there has been direct infringement of these claims by another party.
- Whether Counter-Defendants took action that was intended to cause, and led to, the other party's infringing actions during the time the '851 Patent was in force.
- Whether Counter-Defendants were aware of the '851 Patent and knew that the other party's acts would infringe the '851 Patent.
- Whether any alleged belief of noninfringement by Counter-Defendants was reasonable.

4. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants contribute to infringement of claims 1 and 2 of the '851 Patent, including:

- Whether there has been direct infringement of these claims by another party.
- Whether Counter-Defendants sold in, offered to sell in, and/or imported into the United States a component of the claimed composition of the '851 Patent.
- Whether Counter-Defendants' component is a material part of the claimed composition of the '851 Patent.

[1] The Wilton Patents refer to U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827. Specifically, Counter-Plaintiffs assert claims 1 and 2 of the '851 Patent, claims 1 and 2 of the '590 Patent, and claims 1 and 2 of the '827 Patent ("Asserted Claims of the Wilton Patents") against Counter-Defendants.

- Whether Counter-Defendants were aware of the '851 Patent and knew that their component was especially made or adapted for use in a manner that would infringe the '851 Patent.

- Whether Counter-Defendants' component is not a staple article of commerce capable of substantial non-infringing use.

B. U.S. Patent No. 10,227,590

5. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Viltepso® (viltolarsen) literally meets each and every limitation of claims 1 and 2 of U.S. Patent No. 10,227,590 ("the '590 Patent").

6. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants directly infringe claims 1 and 2 of the '590 Patent by importing, offering to sell, and/or selling Viltepso® (viltolarsen) in the United States.

7. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants induce infringement of claims 1 and 2 of the '590 Patent, including:

- Whether there has been direct infringement of these claims by another party.

- Whether Counter-Defendants took action that was intended to cause, and led to, the other party's infringing actions during the time the '590 Patent was in force.

- Whether Counter-Defendants were aware of the '590 Patent and knew that the other party's acts would infringe the '590 Patent.

8. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants contribute to infringement of claims 1 and 2 of the '590 Patent, including:

- Whether there has been direct infringement of these claims by another party.

- Whether Counter-Defendants sold in, offered to sell in, and/or imported into the United States a component of the claimed composition of the '590 Patent.

- Whether Counter-Defendants' component is a material part of the claimed composition of the '590 Patent.

- Whether Counter-Defendants were aware of the '590 Patent and knew that their component was especially made or adapted for use in a manner that would infringe the '590 Patent.

- Whether Counter-Defendants' component is not a staple article of commerce capable of substantial non-infringing use.

C. U.S. Patent No. 10,266,827

9. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that the use of Viltepso® (viltolarsen) in accordance with the Viltepso® Label literally meets each and every limitation of claims 1 and 2 of U.S. Patent No. 10,266,827 ("the '827 Patent").

10. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants induce infringement of claims 1 and 2 of the '827 Patent, including:

- Whether there has been direct infringement of these claims by another party.

- Whether Counter-Defendants took action that was intended to cause, and led to, the other party's infringing actions during the time the '827 Patent was in force.

- Whether Counter-Defendants were aware of the '827 Patent and knew that the other party's acts would infringe the '827 Patent.

11. Whether Counter-Plaintiffs have proven by a preponderance of the evidence that Counter-Defendants contribute to infringement of claims 1 and 2 of the '827 Patent, including:

- Whether there has been direct infringement of these claims by another party.

- Whether Counter-Defendants sold in, offered to sell in, and/or imported into the United States a material that can be used in practicing the claimed methods of the '827 Patent.

- Whether Counter-Defendants' material is a material part of the claimed methods of the '827 Patent.

- Whether Counter-Defendants were aware of the '827 Patent and knew that their material was especially made or adapted for use in a manner that would infringe the '827 Patent.

- Whether the material is not a staple article of commerce capable of substantial non-infringing use.

II. DAMAGES FOR COUNTER-DEFENDANTS' INFRINGEMENT OF THE WILTON PATENTS

12. The amount of damages in the form of lost profits to which Counter-Plaintiffs are entitled, as proven by a preponderance of the evidence, to compensate for Counter-Defendants' infringement of the Asserted Claims of the Wilton Patents.

13. The amount of damages in the form of a reasonable royalty to which Counter-Plaintiffs are entitled, as proven by a preponderance of the evidence, to compensate for Counter-Defendants' infringement of the Asserted Claims of the Wilton Patents.

14. Whether Counter-Plaintiffs have proven by a preponderance of evidence that Counter-Defendants willfully infringed any of the Asserted Claims of the Wilton Patents.

15. Whether Counter-Plaintiffs are entitled to enhanced damages, which is for the Court to determine post-trial, and on which the parties will submit briefing during post-trial motions.

16. Whether this case is exceptional and Counter-Plaintiffs should be awarded attorneys' fees, which is for the Court to determine post-trial, and on which the parties will submit briefing during post-trial motions.

17. The rate of prejudgment interest to which Counter-Plaintiffs are entitled and whether it should be compounded, which are issues for the Court to determine after trial, and on which the parties will submit briefing during post-trial motions.

18. The costs to which Counter-Plaintiffs are entitled, which is for the Court to determine post-trial, and on which the parties will submit briefing during post-trial motions.

III. BREACH OF CONTRACT BY NS JAPAN

19. Whether Sarepta has proven by a preponderance of evidence that NS Japan materially breached the MCA.

20. The amount of damages to which Sarepta is entitled, as proven by a preponderance of the evidence, to compensate for NS Japan's material breach of the MCA.

IV. INVALIDITY OF THE NS PATENTS[2]

A. Person of Ordinary Skill in the Art ("POSA") as of August 31, 2011

21. The qualification and experience of a POSA.

B. Anticipation Under 35 U.S.C. § 102

22. Whether Sarepta has established by clear and convincing evidence that each of claims 1-3 of the '092 Patent is invalid as anticipated by Popplewell et al., U.S. Patent Publication No. 2010/0168212 ("Popplewell US '212").

23. Whether Sarepta has established by clear and convincing evidence that each of claims 1 and 2 of the '461 Patent is invalid as anticipated by Popplewell US '212.

24. Whether Sarepta has established by clear and convincing evidence that each of claims 1 and 2 of the '106 Patent is invalid as anticipated by Popplewell US '212.

25. Whether Sarepta has established by clear and convincing evidence that each of claims 1-12 of the '741 Patent is invalid as anticipated by Popplewell US '212.

26. Whether Sarepta has established by clear and convincing evidence that each of claims 1-4 of the '217 Patent is invalid as anticipated by Popplewell US '212.

27. What Popplewell US '212 discloses.

28. The level of ordinary skill in the art as of August 31, 2011.

29. What a POSA would have reasonably understood or inferred from reading Popplewell US '212, including options a POSA would at once envisage.

[2] The NS Patents refer to U.S. Patent Nos. 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; and 10,683,322.

30. Whether a POSA would have reasonably understood or inferred from Popplewell US '212 that each and every element of the subject matter claimed by the '092, '461, '106, '741, and '217 Patents is disclosed in Popplewell US '212.

C. Obviousness Under 35 U.S.C. § 103

31. Whether Sarepta has established by clear and convincing evidence that each of claims 1-3 of the '092 Patent is invalid as obvious.

32. Whether Sarepta has established by clear and convincing evidence that each of claims 1 and 2 of the '461 Patent is invalid as obvious.

33. Whether Sarepta has established by clear and convincing evidence that each of claims 1 and 2 of the '106 Patent is invalid as obvious.

34. Whether Sarepta has established by clear and convincing evidence that each of claims 1-12 of the '741 Patent is invalid as obvious.

35. Whether Sarepta has established by clear and convincing evidence that each of claims 1-4 of the '217 Patent is invalid as obvious.

36. Whether Sarepta has established by clear and convincing evidence that each of claims 1-4 and 6-9 of the '322 Patent is invalid as obvious.

37. The scope and content of the prior art.

38. The level of ordinary skill in the art as of August 31, 2011.

39. The differences, if any, between: (1) the subject matter claimed by the NS Patents; and (2) the following prior art references, alone or in combination:

- Popplewell et al., "Comparative Analysis of Antisense Oligonucleotide Sequences Targeting Exon 53 of the Human *DMD* Gene: Implications for Future Clinical Trials," Neuromuscul. Disord. (2010) 20(2):102-110 ("Popplewell 2010");
- Sazani et al., "Safety Pharmacology and Genotoxicity Evaluation of AVI-4658," Int. J. Toxicol. (2010) 29(2):143-156 ("Sazani 2010"); and

- Reeves et al., International Patent Publication No. WO 2009/064471 ("Reeves PCT '471").

40. Whether, in view of the prior art as a whole and the general knowledge in the art, a POSA would have had a reason to modify or combine the teachings of the prior art listed above to obtain the subject matter claimed by the NS Patents with a reasonable expectation of success.

41. Whether, in view of a design need or market pressure to solve a problem and a finite number of identified, predictable solutions in the prior art, the subject matter claimed by the NS Patents would have been obvious to try.

42. Whether there is a nexus between the subject matter claimed by the NS Patents and any alleged objective indicia of nonobviousness, including commercial success, failure of others, long felt unmet need, industry praise, and unexpected results.

43. Whether near simultaneous invention by other researchers of the subject matter claimed by the NS Patents indicates that the subject matter would have been obvious to a POSA.

D. Lack of Written Description Under 35 U.S.C. § 112, First Paragraph

44. Whether Sarepta has established by clear and convincing evidence that each of claims 1-3 of the '092 Patent is invalid for lack of written description.

45. Whether Sarepta has established by clear and convincing evidence that each of claims 1 and 2 of the '461 Patent is invalid for lack of written description.

46. Whether Sarepta has established by clear and convincing evidence that each of claims 1 and 2 of the '106 Patent is invalid for lack of written description.

47. Whether Sarepta has established by clear and convincing evidence that each of claims 1-12 of the '741 Patent is invalid for lack of written description.

48. Whether Sarepta has established by clear and convincing evidence that each of claims 1-4 of the '217 Patent is invalid for lack of written description.

49. Whether Sarepta has established by clear and convincing evidence that each of claims 1-4 and 6-9 of the '322 Patent is invalid for lack of written description.

50. Whether the "invention" described in the NS Patents encompasses a phosphorodiamidate morpholino oligomer that is 25 bases in length, contains thymine bases, and is 100% complementary to positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA.

51. Whether a POSA reading the specification of the NS Patents would have recognized that the named inventors of the NS Patents were in possession of the subject matter claimed by the NS Patents as of August 31, 2011.

V. UNENFORCEABILITY OF THE NS PATENTS

52. Whether Sarepta has established by clear and convincing evidence that the '092 Patent is unenforceable due to inequitable conduct.

53. Whether Sarepta has established by clear and convincing evidence that the '461 Patent is unenforceable due to inequitable conduct.

54. Whether Sarepta has established by clear and convincing evidence that the '106 Patent is unenforceable due to inequitable conduct.

55. Whether Sarepta has established by clear and convincing evidence that the '741 Patent is unenforceable due to inequitable conduct.

56. Whether Sarepta has established by clear and convincing evidence that the '217 Patent is unenforceable due to inequitable conduct.

57. Whether Sarepta has established by clear and convincing evidence that the '322 Patent is unenforceable due to inequitable conduct.

A. The Alleged "Superior Skipping Activity" of the Claimed Subject Matter Over the "Top Performer" Taught in Popplewell 2010

58. Whether Naoki Watanabe (named inventor of the NS Patents), Zhengyu Feng (counsel who prosecuted the NS Patents and other patents that claim priority to International Patent Application No. PCT/JP2011/070318), and/or Mami Hino (counsel at a law firm known as Abe, Ikubo & Katayama, a.k.a. AIK) committed inequitable conduct by making material misrepresentations and omitting material information during prosecution of the NS Patents at the United States Patent and Trademark Office ("USPTO").

59. Whether Naoki Watanabe, Zhengyu Feng, and/or Mami Hino withheld test results from the USPTO showing that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA did not exhibit superior skipping activity over a 30-mer ASO targeting positions 30 to 59 of exon 53 of the human dystrophin pre-mRNA and corresponding to PMO-G disclosed in Popplewell 2010 (a.k.a. "the top performer taught in Popplewell").

60. Whether Naoki Watanabe, Zhengyu Feng, and/or Mami Hino withheld test results from the USPTO showing that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA is inferior to a 25-mer ASO targeting positions 35 to 59 of exon 53 of the human dystrophin pre-mRNA and corresponding to PMO-A disclosed in Popplewell 2010.

61. Whether Naoki Watanabe, Zhengyu Feng, and/or Mami Hino withheld test results from the USPTO showing that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA did not exhibit superior skipping activity over a 25-mer ASO targeting positions 23 to 47 of exon 53 of the human dystrophin pre-mRNA and corresponding to an ASO disclosed in Sazani et al., International Patent Publication No. WO 2010/048586 ("Sazani PCT '586").

62. Whether Naoki Watanabe, Zhengyu Feng, and/or Mami Hino made misrepresentations to the USPTO in contending, *inter alia*, that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA "ha[s] superior skipping activity over exemplary oligomers" disclosed in the prior art, "particularly the top performer taught in Popplewell."

63. Whether the omitted test results and the misrepresentations by Naoki Watanabe, Zhengyu Feng, and/or Mami Hino are material to the patentability of the NS Patents.

64. Whether the USPTO would not have allowed the claims of the NS Patents had it been aware of the omitted test results and the misrepresentations by Naoki Watanabe, Zhengyu Feng, and/or Mami Hino.

65. Whether Naoki Watanabe, Zhengyu Feng, and/or Mami Hino repeatedly withheld information from and made misrepresentations to the USPTO and patent offices in other countries, including:

- omitting test results obtained from the 30 and/or 300 nM concentrations from Figures 9-17 of the NS Patents, despite conducting the experiments underlying one or more figures, supervising Youhei Satou who conducted the remaining experiments, and drafting the specification of the NS Patents.

- withholding test results from the USPTO showing that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA did not exhibit superior skipping activity over prior art ASOs.

- misrepresenting to the USPTO that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA "ha[s] superior skipping activity over exemplary oligomers" disclosed in the prior art, "particularly the top performer taught in Popplewell."

- withholding test results from the European Patent Office showing that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA did not have a higher skipping efficiency than a 30-mer ASO targeting positions 33 to 62 of exon 53 of the human dystrophin pre-mRNA, corresponding to PMO-H disclosed in Popplewell 2010.

- misrepresenting to the European Patent Office that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA "has a higher skipping efficiency" than an ASO corresponding to PMO-H disclosed in Popplewell 2010.

- withholding test results from the Japanese Patent Office showing that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA did not exhibit superior skipping activity over prior art ASOs.

- misrepresenting to the Japanese Patent Office in Japan that a 25-mer ASO targeting positions 36 to 60 of exon 53 of the human dystrophin pre-mRNA "is [more] highly active than" an ASO corresponding to PMO-G disclosed in Popplewell 2010.

- withholding test results from the European Patent Office showing that ASOs falling within the claim scope of the Wilton Patents exhibit high skipping activities.

- misrepresenting to the European Patent Office that "the invention [of the European counterpart of the Wilton Patents] cannot be worked successfully over the whole scope of the claim."

66. In addition, whether Naoki Watanabe, Zhengyu Feng, and/or Mami Hino submitted a declaration of Toshihiro Ueda to the USPTO during prosecution of U.S. Patent No. 11,028,122, which claims priority to International Patent Application No. PCT/JP2011/070318 as the NS Patents do, despite:

- Toshihiro Ueda's declaration, which was submitted to the European Patent Office, inaccurately attested that he is "the person that supervised and was responsible for the experiments" even though Toshihiro Ueda admitted that he never performed any experiment evaluating a phosphorodiamidate morpholino oligomer targeting human exon 53 in cells and that he did not supervise the experiments of Naoki Watanabe between 2009 and 2015.

67. Whether Naoki Watanabe, Zhengyu Feng, and/or Mami Hino made material misrepresentations and/or omitted material information with the specific intent to deceive the USPTO.

68. Whether a specific intent to deceive the USPTO is the single most reasonable inference able to be drawn from the evidence, including the repeated practice of Naoki Watanabe,

Zhengyu Feng, and/or Mami Hino in withholding information from and making misrepresentations to the USPTO and patent offices in other countries.

B. Nondisclosure of Sazani 2010

69. Whether Naoki Watanabe (named inventor of the NS Patents) committed inequitable conduct by withholding Sazani 2010 from the USPTO during prosecution of the NS Patents.

70. Whether Naoki Watanabe was aware of Sazani 2010 at least as of July 2010.

71. What Sazani 2010 discloses.

72. Whether Sazani 2010 is material to the patentability of the NS Patents.

73. Whether the USPTO would not have allowed the claims of the NS Patents had it been aware of Sazani 2010.

74. Whether Sazani 2010 is cumulative with Sazani PCT '586"; Bennett et al., U.S. Patent Publication No. 2012/0190728 ("Bennett US '728"); Wilton et al., International Patent Publication No. WO 2006/000057 ("Wilton PCT '057"); Weller et al., International Patent Publication No. WO 2008/036127 ("Weller PCT '127"); Wilton et al., International Patent Publication No. WO 2011/057350 ("Wilton PCT '350"); Popplewell 2010.

75. Whether each of Reeves PCT '471; Moulton and Jiang, "Gene Knockdowns in Adult Animals: PPMOs and Vivo-Morpholinos," Molecules (2009) 14(3):1304-1323 ("Moulton 2009"); Kinali et al., "Local Restoration of Dystrophin Expression with the Morpholino Oligomer AVI-4658 in Duchenne Muscular Dystrophy: A Single-Blind, Placebo-Controlled, Dose-Escalation, Proof-of-Concept Study," Lancet Neurol. (2009) 8(10):918-928 ("Kinali 2009"); and Arora et al., "Neutrally Charged Phosphorodiamidate Morpholino Antisense Oligomers: Uptake, Efficacy and Pharmacokinetics," Curr. Pharm. Biotechnol. (2004) 5(5):431-439 ("Arora 2004") was submitted to the USPTO during prosecution of the NS Patents.

76. Whether Sazani 2010 is cumulative with Reeves PCT '471; Moulton 2009; Kinali 2009; and Arora 2004.

77. Whether Naoki Watanabe withheld Sazani 2010 from the USPTO during prosecution of the NS Patents with a specific intent to deceive the USPTO.

78. Whether a specific intent to deceive the USPTO is the single most reasonable inference able to be drawn from the evidence, including Naoki Watanabe's recognition that the teachings of Sazani 2010 were important to NS Japan's exon 53 program, including Sazani 2010's disclosure of the safety and genotoxicity profiles of AVI-4658 in mice and non-human primates as well as AVI-4658's precise chemical structure, the reliance on Sazani 2010 in named inventor Dr. Shin'ichi Takeda's work outside of litigation, the wide distribution of Sazani 2010 within NS Japan, and the repeated practice of Naoki Watanabe withholding information from and making misrepresentations to the USPTO and patent offices in other countries.